



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-2872]

Medical Device User Fee Amendments; Public Meeting; Request for Comments; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment period for the Medical Device User Fee Amendments (MDUFA) reauthorization draft recommendations that were announced in the Federal Register on October 7, 2016. In that Federal Register notice, FDA requested comments on the draft recommendations related to the reauthorization of the medical device user fee amendments. The Agency is taking this action to allow interested persons the statutorily required 30 days to submit comments.

DATES: FDA is extending the comment period on the MDUFA reauthorization draft recommendations published October 7, 2016 (81 FR 69829). Submit either electronic or written comments by November 28, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your

comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2016-N-2872 for "Medical Device User Fee Amendments; Public Meeting; Request for Comments; Extension of Comment Period." Received comments will be placed in the docket and, except for those

submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:  
<http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the

prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Aaron Josephson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5449, Silver Spring, MD 20993, 301-796-5178, Aaron.Josephson@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the Federal Register of October 7, 2016, FDA published a request for comments with a 30-day comment period beginning October 14, 2016, to request comments on MDUFA reauthorization draft recommendations.

Because the Agency was unable to post the draft recommendations until October 25, 2016, and the statute requires a period of 30 days be provided for the public to provide comments on the draft recommendations, FDA is extending the comment period for the MDUFA reauthorization draft recommendations until November 28, 2016.

Dated: October 27, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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